



Atty. Dkt. No. 065334-0111

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Jacob Mathiesen

Title: METHOD FOR MUSCLE
DELIVERY OF DRUGS,
NUCLEIC ACIDS AND OTHER
COMPOUNDS

Appl. No.: 10/620,271

Filing Date: July 14, 2003

Examiner:

Art Unit:

CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450, on the date below. <u>DIANE GARCIA</u> (Printed Name) <u><i>Diane Garcia</i></u> (Signature) <u>10-14-03</u> (Date of Deposit)

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

Applicants submit herewith a copy of the Form PTO/SB/08 which was submitted to the U.S. PTO in related application Serial No. 10/345,410 filed 01/16/2003. As provided in 37 CFR §1.98(d), copies of the documents listed on the form are not being provided since they were previously submitted to the United States Patent & Trademark Office for this related application.

Also submitted herewith is a second Form PTO/SB/08 with an additional document that has come to the attention of the Applicants. A copy of this document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR

§1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

The documents are in English..

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of all forms be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

Date 10/13/03

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By Barry Wilson

Barry S. Wilson

Attorney for Applicant

Registration No. 39,431

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INFORMATION DISCLOSURE
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Date Submitted: July 18, 2003

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2 of 7

Complete if Known

Application Number	10/345,410
Filing Date	01/16/2003
First Named Inventor	Bjarne BOGEN
Group Art Unit	1645
Examiner Name	Unknown
Attorney Docket Number	065334-0109

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A9	Aase, et al., "The use of a hapten-Fab conjugate to sensitize target cells for antibody-dependent complement-mediated lysis and antibody-dependent cell-mediated cytotoxicity," <i>J. Immunol. Methods</i> <u>136</u> , 185-191 (1991)	
	A10	Abe, et al., "Induction of humoral and cellular anti-idiotypic immunity by intradermal injection of naked DNA encoding a human variable region gene sequence of an immunoglobulin heavy chain in a B cell malignancy," <i>Gene Ther</i> <u>3</u> :988-993 (1996)	
	A11	Acsadi et al., "Human dystrophin expression in mdx mice after intramuscular injection of DNA constructs," <i>Nature</i> <u>352</u> , 815 (1991)	
	A12	Arafat, et al., "Effective single chain antibody (scFv) concentrations in vivo via adenoviral vector mediated expression of secretory scFv," <i>Gene Ther</i> <u>9</u> :256-262 (2002)	
	A13	Biragyn, et al., "B-cell malignancies as a model for cancer vaccines: from prototype protein to next generation genetic chemokine fusions," <i>Immunol Rev</i> <u>170</u> :115-126 (1999)	
	A14	Bogen and Weiss, "Processing and Presentation of Idiotypes to MHC-Restricted T Cells," <i>Int. Rev. Immunol.</i> <u>10</u> , 337-355 (1993)	
	A15	Bogen, et al., "Idiotope-specific T cell clones that recognize syngeneic immunoglobulin fragments in the context of class II molecules," <i>Eur. J. Immunol.</i> <u>16</u> , 1373-1378 (1986)	
	A16	Chang & Prud'Homme, "Intramuscular Administration of Expression Plasmids Encoding Interferon- γ Receptor/IgG1 or IL-4/IgG1 Chimeric Proteins Protects from Autoimmunity," <i>The Journal of Gene Medicine</i> , <u>1</u> :415-423 (1999)	
	A17	Chang, et al., "A Single Intramuscular Injection of Recombinant Plasmid DNA Induces Protective Immunity and Prevents Japanese Encephalitis in Mice," <i>Journal of Virology</i> , <u>74</u> (9):4244-4252 (2000)	
	A18	Colombat, et al., "Rituximab (anti-CD20 monoclonal antibody) as single first-line therapy for patients with follicular lymphoma with a low tumor burden: clinical and molecular evaluation," <i>Blood</i> <u>97</u> , 101-106 (2001)	
	A19	Donoghue, et al., "Rostrocaudal gradient of transgene expression in adult skeletal muscle," <i>Proc. Natl. Acad. Sci., USA</i> <u>88</u> :5847-5851 (1991)	
	A20	Eidem, et al., "Recombinant antibodies as carrier proteins for sub-unit vaccines: influence of mode of fusion on protein production and T-cell activation," <i>Journal of Immunological Methods</i> , <u>245</u> :119-131 (2000)	

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Sheet 3 of 7

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	A21	Feldmann, et al., "Discovery of TNF- α as a therapeutic target in rheumatoid arthritis: preclinical and clinical studies," <i>Joint Bone Spine</i> 69:12-18 (2002)	
	A22	Forconi, et al., "Insight into the potential for DNA idiotype fusion vaccines designed for patients by analysing xenogeneic anti-idiotype antibody responses," <i>Immunology</i> 107:39-45 (2002)	
	A23	Huston, et al., "Protein engineering of antibody binding sites: Recovery of specific activity in an anti-digoxin single-chain Fv analogue produced in <i>Escherichia coli</i> ," <i>Proc. Nat'l Acad. Sci. USA</i> , 85:5879-5883 (1988)	
	A24	King, et al., "DNA vaccines with single-chain Fv fused to fragment C of tetanus toxin induce protective immunity against lymphoma and myeloma," <i>Nat Med</i> 4:1281-1286 (1998)	
	A25	Kwak LW, "Translational development of active immunotherapy for hematologic malignancies," <i>Int J Hematol</i> 76(Suppl 1):320-321 (2002)	
	A26	Lang, et al., "On immunoglobulin heavy chain gene switching: two 2b genes are rearranged via switch sequences in MP-11 cells but only one is expressed," <i>Nucleic Acids Res.</i> 10:611-630 (1982)	
	A27	Lauritzsen, et al., "Idiotypic-Specific, Major Histocompatibility Complex Restricted T Cells are of both Th1 and Th2 Type," <i>Scand. J. Immunol.</i> 33:647-656 (1991)	
	A28	Lee, et al., "Surfactant-induced sealing of electroporated skeletal muscle membranes <i>in vivo</i> ," <i>Proc. Nat'l Acad. Sci. USA</i> 89:4524-4528 (1992)	
	A29	Leonard, et al., "Anti-human epidermal growth factor receptor 2 monoclonal antibody therapy for breast cancer," <i>Br. J. Surg.</i> 89:262-271 (2002)	
	A30	Lewis, et al., "Generation of neutralizing activity against human immunodeficiency virus type 1 in serum by antibody gene transfer," <i>J Virol.</i> 76:8769-8775 (2002)	
	A31	Lunde, et al., "Efficient Delivery of T Cell Epitopes to APC by Use of MHC Class II-Specific - - - - - Troybodies," <i>J. Immunol.</i> 168, 2154-2162 (2002)	
	A32	Lunde, et al., "Immunoglobulin as a Vehicle for Foreign Antigenic Peptides Immunogenic to T Cells," <i>Molecular Immunology</i> 34:1167-1176 (1997)	
	A33	Lunde, et al., "Antibodies engineered with IgD specificity efficiently deliver integrated T-cell epitopes for antigen presentation by B cells," <i>Nature Biotechnology</i> 17:670-675 (1999)	

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	A34	Mathiesen, I, "Electroporation of skeletal muscle enhances gene transfer <i>in vivo</i> ," <i>Gene Therapy</i> 6(4):508-514 (1999)			
	A35	Michaelsen, et al., "Enhancement of Complement Activation and Cytolysis of Human IgG3 by Deletion of Hinge Exons," <i>Scand. J. Immunol.</i> 32:517-528 (1990)			
	A36	Muscat, et al., "Multiple 5'-Flanking Regions of the Human α -Skeletal Actin Gene Synergistically Modulate Muscle-Specific Expression" <i>Mol. Cell. Biol.</i> 7: 4089-4099 (1987)			
	A37	Neuberger, M., "Expression and regulation of immunoglobulin heavy chain gene transfected into lymphoid cells," <i>EMBO J.</i> 2:1373-1378 (1983)			
	A38	Noël, et al., "Skin as a potential organ for ectopic monoclonal antibody production," <i>The Journal of Investigative Dermatology</i> , 118:288-294 (2002a)			
	A39	Noël, et al., "Sustained Systematic Delivery of Monoclonal Antibodies by Genetically Modified Skin Fibroblasts," <i>The Journal of Investigative Dermatology</i> , 115(4):740-745 (2000)			
	A40	Noël, et al., "High <i>in vivo</i> production of a model monoclonal antibody on adenoviral gene transfer," <i>Hum Gene Ther</i> 13:1483-1493 (2002b)			
	A41	Noël, et al., "In vitro and in vivo secretion of cloned antibodies by genetically modified myogenic cells," <i>Hum Gene Ther</i> 8:1219-1229 (1997)			
	A42	Norderhaug, et al, "Versatile vectors for transient and stable expression of recombinant antibody molecules in mammalian cells," <i>J. Immunol. Methods</i> 204:77-87 (1997)			
	A43	Ozato, et al., "Hybridoma Cell Lines Secreting Monoclonal Antibodies to Mouse H-2 and Ia Antigens," <i>J. Immunol.</i> 124:533-540 (1980)			
	A44	Pelegri, et al., "Immunotherapy of a Viral Disease by in Vivo Production of Therapeutic Monoclonal Antibodies," <i>Human Gene Therapy</i> 11:1407-1415 (2000)			

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	A45	Piccirillo & Prud'Homme, "Prevention of Experimental Allergic Encephalomyelitis by Intramuscular Gene Transfer with Cytokine-Encoding Plasmid Vectors," <i>Human Gene Therapy</i> <u>10</u> :1915-1922 (1999)	
	A46	Rice, et al., "Critical components of a DNA fusion vaccine able to induce protective cytotoxic T cells against a single epitope of a tumor antigen," <i>J Immunol</i> <u>169</u> :3908-3913 (2002)	
	A47	Rice, et al., "Manipulation of pathogen-derived genes to influence antigen presentation via DNA vaccines," <i>Vaccine</i> <u>17</u> :3030-3038 (1999)	
	A48	Rinaldi, et al., "Antibodies elicited by naked DNA vaccination against the complementary-determining region 3 hypervariable region of immunoglobulin heavy chain idiotype determinants of B-lymphoproliferative disorders specifically react with patients' tumor cells," <i>Cancer Res</i> <u>61</u> :1555-1562 (2001)	
	A49	Rizzuto, et al., "Efficient and regulated erythropoietin production by naked DNA injection and muscle electroporation," <i>Proc. Nat'l Acad. Sci. USA</i> <u>96</u> (11):6417-6422 (1999)	
	A50	Rosenberg, et al., "Gene Transfer into Humans - Immunotherapy of Patients with Advanced Melanoma, Using Tumor-Infiltrating Lymphocytes Modified by Retroviral Gene Transduction," <i>New Eng. J. Med.</i> <u>323</u> :570-578 (1990)	
	A51	Ruffini, et al., "Recent advances in multiple myeloma immunotherapy," <i>Biomed Pharmacother</i> <u>56</u> :129-132 (2002)	
	A52	Ruffini, et al., "Idiotype vaccination for B-cell malignancies as a model for therapeutic cancer vaccines: from prototype protein to second generation vaccines," <i>Haematologica</i> <u>87</u> (9):989-1001 (2002)	
	A53	Smith & Nordstrom, "Advances in plasmid gene delivery and expression in skeletal muscle," <i>Current Opinion in Molecular Therapeutics</i> <u>2</u> (2):150-154 (2000)	

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	A54	Sternberg, et al., "Identification of Upstream and Intragenic Regulatory Elements That Confer Cell-Type-Restricted and Differentiation-Specific Expression on the Muscle Creatine Kinase Gene," <i>Mol. Cell. Biol.</i> <u>8</u> (7):2896-2909 (1988)	
	A55	Stevenson, et al., "DNA vaccines against cancer: from genes to therapy," <i>Ann Oncol</i> <u>10</u> :1413-1418 (1999)	
	A56	Stevenson, et al., "DNA vaccines against haematological malignancies," <i>Haematologica</i> <u>84</u> (Suppl EHA-4):11-13 (1999)	
	A57	Stevenson, et al., "DNA vaccination against multiple myeloma," <i>Semin Hematol</i> <u>36</u> :38-42 (1999)	
	A58	Stevenson, et al., "Idiotypic DNA vaccines against B-cell lymphoma," <i>Immunol Rev</i> <u>145</u> :211-228 (1995)	
	A59	Stevenson, et al., "New strategies for vaccination and immunomodulation in NHL," <i>Ann Hematol</i> <u>80</u> (Suppl 3):B132-B134 (2001)	
	A60	Synguelas, et al., "DNA immunization induces protective immunity against B-cell lymphoma," <i>Nat Med</i> <u>2</u> :1038-1041 (1996)	
	A61	Synguelas, et al., "DNA vaccination against the idotype of a murine B cell lymphoma: mechanism of tumor protection," <i>J Immunol</i> <u>162</u> :4790-4795 (1999)	
	A62	Tao, et al., "Role of Carbohydrate in the Structure and Effector Functions Mediated by the Human IgG constant Region," <i>J. Immunol.</i> <u>143</u> , 2595-2601 (1989)	
	A63	Thirdborough, et al., "Vaccination with DNA encoding a single-chain TCR fusion protein induces antitumor immunity and protects against T-cell lymphoma," <i>Cancer Res</i> <u>62</u> :1757-1760 (2002)	
	A64	Timmerman, et al., "Idiotypic-encoding recombinant adenoviruses provide protective immunity against murine B-cell lymphomas," <i>Blood</i> <u>97</u> (5):1370-1377 (2001)	

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	A65	Tsuji-Yamada, et al., "Effect of IL-12 encoding plasmid administration on tight-skin mouse," <i>Biochem Biophys Res. Commun.</i> , 280(3):707-712 (2001)	
	A66	Wolff, et al., "Direct Gene Transfer into Mouse Muscle in Vivo," <i>Science</i> 247:1465-1468 (1990)	
	A67	Zhu, et al., "DNA fusion vaccines against B-cell tumors," <i>Trends Mol Med</i> 7:566-572 (2001)	
	A68	Hofmann, "Cells in electric fields," in E. Neumann, A.E. Sowers, & C.A. Jordan (eds.), <i>ELECTROPORATION AND ELECTROFUSION IN CELL BIOLOGY</i> , pages 389-407 (Plenum Publ. Corp. 1989)	
	A69	Kabat, et al., <i>SEQUENCES OF PROTEINS OF IMMUNOLOGICAL INTEREST</i> , 4th ed. U.S. Dept. Health and Human Services, Public Health Services, Bethesda, Md. (1987)	
	A70	Williams and Barclay, <i>IMMUNOGLOBULIN GENES</i> (page 361), Academic Press, New York (1989)	

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	A1	US 2003/0018006 A1		Tao et al.	01-23-2003	

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